K093872

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance the requirements of 21 CFR 807.92

The Assigned 510(k) Number is: Pending

MAR 31 2010

1. Submitter Information

- **Manufacturer Name and Address:**
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  Beijing, China 100039

  Beijing Choice Electronic Technology Co., Ltd.
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  Beijing, China 100041

- **Contact Person:**
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- **Date prepared:**
  October 22, 2009

2. Applicant Device Information

Trade/Proprietary Name: Handheld ECG Monitor MD100
Common Name: Handheld, ECG Monitor
Classification: 21 CFR 870.2340 **Oximeter Class:** II

3. Legally Marketed Predicate Device

Omron HCG-801 Portable ECG Monitor
K060766
Omron Healthcare, Inc.

4. Device Description

The applicant device of Handheld ECG Monitor MD100 is a handheld device, which can records cardiac event data and displays the data in a clear and precise waveform. The ECG Monitor is made up of signal input unit, signal amplify unit, CPU, Display unit, power unit and storage chip.

The MD100 Handheld ECG Monitor is activated by the user whenever symptoms are experienced. The recorded data serves as reliable evidence and are later shown to user or physicians or other health care professionals for confirmation of these symptoms.
When a user feels that a cardiac event is occurring, the utilization of MD100 has the feature of recording this real time data that is normally difficult to capture. When tested, the Heart Rate Value is displayed.

The applicant device has "data upload" function which controlled by hardware, it can transmit the data measured by the device to computer via the USB port. The software attached with the device named " Keep-it-easy" in CD ROM, which is use for store and playback the data collected by MD100 ECG monitor. The "Keep-it-easy" software needs to install in the computer by user. The "Keep-it-Easy" software CD ROM is the accessory of the applicant device.

The applicant device has low battery voltage indication function. The power of the monitor works supplied by 2*AAA batteries.

5. Indications for Use

The device is a handheld, personal electrocardiograph unit, which can measure electrical activities of the heart easily and conveniently. It is immediately available at any time to manually record transient cardiac events, suitable for hospital or home health care use, which can detect, display and store ECG signal, and if possible, provide average heart rate message after ECG measurement. The users can use it themselves to check their heart condition.

It is suitable for the adult users, who suffers from cardio-vascular diseases, or the adult people who are caring about their heart working conditions during their daily life. This device is not intended for use as a conventional diagnostic tool, but use as a healthcare tool which can provide doctor the recorded data as references.

The product is not a conventional diagnostic tool.

6. Effectiveness and Safety Considerations

The applicant device is compliance with IEC60601-1, Medical electrical equipment - Part 1: General requirements for safety and IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for safety -Collateral standard: Electromagnetic compatibility -. Requirements and tests.

The applicant device is compliance with AAMI EC38 Ambulatory Electrocardiographs for the basic safety and essential performance for medical use.

The Software Validation is in compliance with FDA Guidance to Compliance with FDA Guidance for the Content of PreMarket Submissions for Software Contained in Medical Devices.

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The Biological Evaluation Tests are in compliance with the standards of ISO 10993, "Biological Evaluation of Medical Devices".

Bench testing is performed to demonstrate safety and effectiveness and equivalency to the predicate device.

7. Substantially Equivalence Determination

The MD100 Handheld ECG Monitor and the Omron HCG-801 portable ECG Monitor is handheld, portable, personal type ECG monitor. MD100 Handheld ECG Monitor does provide the data transmission option which is not an option the Omron HCG-801 ECG offers. Both devices are prescription devices intended for self-testing by patients under doctors' supervision. In both devices, user can place device on his/her chest and hold it steadily to test although the MD100 Handheld ECG Monitor provides another method that test by the centre of the palm. In both devices the user is not required to apply external electrodes to the body. Both devices have the capability to record real time heart rhythm waveform and heart beat and store data that can be displayed and downloaded.

The MD100 Handheld ECG Monitor constitutes a safe, accurate, and reliable means for recording of ECG data. When this device is used as intended it is as safe and effective as the predicate device. As shown, MD100 device has generally the same technological characteristics and intended use as Omron HCG-801 portable ECG Monitor but more advantageous and practical in terms of ease of use and reliability.

Validation testing contained in the submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety and effectiveness. When the device is used as it is intended it poses no adverse health effects of safety risks to users.

8. Conclusion

Based upon the performance testing and comparison to legally marketed predicate device (for indications for use, technology, and performance) we have demonstrated that the MD100 Handheld ECG Monitor is substantially equivalent in safety and effectiveness to the predicate device.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 31 2010

Beijing Choice Electronic Technology Co., Ltd.
c/o Ms. Yajing Li
No.9 Shuangyuan Rd.
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Shijingshan District
Beijing, China 100041

Re: K093872
Device Name: Handheld ECG Monitor MD100
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (Two)
Product Code: DPS
Dated: December 11, 2010
Received: December 17, 2010

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K093872

Device Name: Handheld ECG Monitor MD100

Indications for Use:

The device is a handheld, personal electrocardiograph unit, which can measure electrical activities of the heart easily and conveniently. It is immediately available at any time to manually record transient cardiac events, suitable for hospital or home health care use, which can detect, display and store ECG signal, and if possible, provide average heart rate message after ECG measurement. The users can use it themselves to check their heart condition.

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The product is not a conventional diagnostic tool.

Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093872